REMARKS

Claims 1-68 are currently pending. Claims 8-35 and 39-68 have been withdrawn from consideration in the present application. Claims 8-35 and 39-68 are herein canceled without prejudice. Claims 1, 4, 36, and 37 are amended herein to clarify the subject matter of the claims. New claims 69-72 are presented herein. Accordingly, claims 1, 4, 36, and 37, as amended, and dependent claims therefrom, including new claims 69-72, are presently under consideration.

Support for amendments to the claims is found throughout the specification and in the original claims. Specifically, support for amendment to claims 1, 4, 36, and 37 is found in original claims 1, 4, 36, and 37; and in Figures 1, 2, 3, and 13A; and at page 5, lines 22-28; at page 6, lines 11-13; at page 8 line 29 through to page 9, line 16; at page 10, lines 9-12; at page 17, line 23 through to page 18, line 4; at page 37, line 23 through to page 38, line 10; and at page 59, lines 10-14, wherein the molecular weights of ISGF-3 polypeptide components and their corresponding amino acid sequences and SEQ ID NO: designations are detailed; and, for example, at page 58, lines 5-9, wherein ISGF-3 is described as a multimeric protein complex. No issue of new matter is introduced via these amendments.

Support for new claims 69-72 is found in the original claims and throughout the specification. Specifically, support for new claims 69-72 is found in original claims 1, 4, 36, and 37, respectively and in the specification at page 42, lines 20-24, wherein support for a composition comprising a receptor recognition factor and an excipient is presented. No issue of new matter is introduced via these amendments.

Applicant herewith amends the specification, in accordance with the Examiner's suggestion, to reflect that the present application is a division of Application No. 08/212,185, filed on March 11, 1994. Applicant also herewith amends the specification to indicate that parent applications of the present invention have either been abandoned or have matured into U.S. Patents. Namely, U.S. Application No. 08/212,185 has matured into U.S. Patent No. 6,605,442. No issue of new matter is introduced by these amendments.

Information Disclosure Statement

The Examiner has indicated that he was unable to locate references lined through on the

initialed PTO-1449, but would consider such references if Applicant were to submit new copies of these references. In accordance with the Examiner's suggestion, new copies of these references are submitted herewith. These references are designated as AA-AO, AQ, AU-AV, AZ, BB-BC, BF, BI, and BS on the Information Disclosure Statement filed in connection with parent application No. 08/212,185.

Priority

The Examiner has noted that the application appears to be a division of prior Application No. 08/212,185, filed on March 11, 1994, but the specification styles this application as a continuation application. The Examiner has indicated that correction is required to reflect that the present application is a division of prior Application No. 08/212,185. Applicant's original designation of the present application as a continuation, rather than a division, of Application No. 08/212,185 was made without deceptive intent. The specification is hereby amended, as suggested by the Examiner, to reflect the relationship by division between the present application and prior Application No. 08/212,185.

Rejections under 35 USC § 112

Claim 1-3, 5-7, 36, and 38 have been rejected under 35 USC § 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s) were in possession of the claimed invention at the time of filing. The Examiner maintains that the rejected claims are allegedly directed to a receptor recognition factor defined by its functional characteristics. In view of the amendments to the claims, the above rejection of claims 1-3, 5-7, 36, and 38 under 35 USC § 112, first paragraph, is believed to be overcome.

Claims 1 and 36 and dependent claims therefrom are amended herein to define that the claimed receptor recognition factor of the present invention consists of three polypeptides: a first polypeptide comprising an amino acid sequence of SEQ ID NO: 2 (human 113 kD protein factor; Stat 2), a second polypeptide comprising an amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 8 (human and murine, respectively, 91 kD protein factor; Stat 1α), and a third polypeptide

comprising an amino acid sequence of SEQ ID NO: 6 (human 84 kD protein factor; Stat 1β).

In view of the above, Applicant asserts that the rejection of claims 1-3, 5-7, 36, and 38 under 35 USC § 112, first paragraph (written description), is obviated, and respectfully requests that the rejection be withdrawn.

Claims 1-3, 5-7, 36, and 38 have been rejected under 35 USC § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is the Examiner's position that the rejected claims allegedly read on ISGF-3 and any other receptor recognition factor having the claimed properties as well as the subunits of ISGF-3. The Examiner acknowledges that the specification is enabling for intact ISGF-3. In view of the amendments to the claims, the rejection of claims 1-3, 5-7, 36, and 38 under 35 USC § 112, first paragraph (enablement), is believed to be overcome.

Claims 1 and 36 and dependent claims therefrom are amended herein to define that the claimed receptor recognition factor of the present invention is an intact ISGF-3 consisting of three polypeptide subunits, wherein a first polypeptide comprises an amino acid sequence of SEQ ID NO: 2, a second polypeptide comprises an amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 8, and a third polypeptide comprises an amino acid sequence of SEQ ID NO: 6.

In view of the above, Applicant asserts that the rejection of claims 1-3, 5-7, 36, and 38 under 35 USC § 112, first paragraph (enablement), is obviated, and respectfully requests that the rejection be withdrawn.

Rejections under 35 USC § 101

Claims 1-7 and 36-38 stand rejected under 35 U.S.C. § 101 because the claimed invention is allegedly not supported by either a specific and substantial asserted utility or a well-established utility. The Examiner states that the utility of ISGF-3 as a whole is not in question. Accordingly, claims 1, 36, and 37 and dependent claims therefrom, are amended herein to indicate that the claims are directed to an ISGF-3 complex consisting of three polypeptide subunits, wherein a first polypeptide comprises an amino acid sequence of SEQ ID NO: 2, a second polypeptide comprises an amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 8, and a

third polypeptide comprises an amino acid sequence of SEQ ID NO: 6. Applicant, therefore, believes that the basis of this rejection is obviated by this amendment, and respectfully requests that the rejection of claims 1-7 and 36-38 be withdrawn.

Rejections under 35 USC § 112

Claims 1-7 and 36-38 are also rejected under 35 U.S.C. § 112, first paragraph, for an alleged lack of enablement. Specifically, the claimed invention is allegedly not supported by either a specific and substantial asserted utility or a well-established utility, thus a skilled artisan would allegedly not know how to use the claimed invention. As indicated herein above, claims 1, 36, and 37 and dependent claims therefrom, are amended herein to indicate that the claims are directed to an intact ISGF-3 consisting of three polypeptide subunits, wherein a first polypeptide comprises an amino acid sequence of SEQ ID NO: 2, a second polypeptide comprises an amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 8, and a third polypeptide comprises an amino acid sequence of SEQ ID NO: 6. The utility of ISGF-3 is fully supported by the specification as acknowledged by the Examiner. Applicant, therefore, believes that the rejection under 35 U.S.C. § 112, first paragraph (enablement), is obviated by this amendment, and respectfully requests that the rejection of claims 1-7 and 36-38 be withdrawn.

Rejections under 35 USC § 102

Claims 1-5 and 36-38 are rejected under 35 USC § 102(b) as allegedly anticipated by Fu et al. (PNAS 87:8555-8559, November 1990). In view of the amendments to the claims and Applicant's arguments herein below, the rejection, as it applied to claims 1-5 and 36-38, is respectfully traversed.

Fu et al. names two of the co-inventors of the present invention as the first and the senior author respectively, and describes an initial attempt to isolate and characterize the receptor recognition factors. The purification of the receptor recognition factors described by Fu et al., however, led to a preparation of insufficient purity and insufficient quantity to perform the detailed characterization disclosed in the instant specification. These deficiencies are underscored by the disclosure of Fu *et al.*, whereby a nine (9) step purification procedure is

taught (see Table 1 of Fu *et al.*) that starts with 0.4 grams of protein and yields only 2.5 μg of a preparation that in its most purified embodiment still contains at least six different proteins [Fu *et al.*, Page 8559, Column 1, first full paragraph]. Notably, ISGF-3 specific components present in the impure preparation of Fu et al. were not present in quantities sufficient for further analysis, such as peptide sequencing, at the publication date of this reference. As further indicated in the Fu et al. reference:

> *"Therefore, of the six major polypeptides present in the peak ISGF3 Mono Q fraction, four were specifically retained as components of the ISGF3-ISRE complex (48, 84, 91, and 113 KDa), and two were present as nonspecific DNA-binding activities."* See page 8558, Column 2, first paragraph.

Until the disclosure of the present invention, therefore, a purified ISGF-3 receptor recognition factor had not been isolated. The presence of two polypeptides that are designated as **two** of the **six major** polypeptides, and which confer nonspecific DNA-binding activities, is entirely corroborative of Applicant's assertion regarding the lack of purity of the preparation described by Fu et al. Moreover, the lack of purity is also evidenced in the biochemical properties of the Fu et al. preparation which include non-specific DNA binding activity not attributable to purified ISGF-3. See Fig. 4B, lanes 4 and 6 of the Fu et al. reference, wherein non-specific DNA binding proteins having molecular weights of approximately 86 kD and 70 kD are shown. Indeed, as noted in the instant specification at page 62, lines 1-5, contaminants having molecular weights of 86 kD and 70 kD that copurify with ISGF-3 using such methodology have been sequenced and identified as the KU antigen, a widely-distributed protein that binds DNA termini. In the specific ISGF-3:ISRE complex, however, there is no KU antigen and therefore, it has been assigned no role in IFN-dependent transcriptional stimulation [Wedrychowski et al. (1990) J Biol. Chem. 265: 21433]. In view of the above, Applicant asserts that structural and functional distinctions exist between the purified receptor recognition factor claimed in the present invention and the impure preparation of Fu et al.

In view of the above arguments, the Examiner is respectfully requested to reconsider the validity of the rejection of the claims under 35 U.S.C. §102 and withdraw the rejection.

Rejections under 35 USC § 103

Claims 6 and 7 are rejected under 35 USC § 103(a) as allegedly unpatentable over Fu et al. (*supra*), presumably in view of knowledge in the field pertaining to labels. In view of the amendments to the claims and Applicant's arguments herein below, the rejection, as it applied to claims 6 and 7, is respectfully traversed.

The deficiencies of the Fu et al. reference with respect to alleged anticipation of the invention, as described above, are equally well applied to the rejection of the above claims on the basis of an alleged obviousness. The Fu et al. reference fails to teach or suggest the claimed isolated receptor recognition factor of the present invention. As described herein above, two contaminant polypeptides are present in sufficient quantities to be referred to by the authors as two of the six **major** polypeptides of the preparation. The preparation of Fu et al. is, therefore, not a purified receptor recognition factor as presently claimed and thus, differs from that of the present invention with respect to the structural components of the preparation. Indeed, these contaminant polypeptides confer upon the preparation of Fu et al. altered functional properties as compared to those of the purified preparation of isolated receptor recognition factor proteins described in the instant application. Applicant, therefore, maintains that a combination of general knowledge pertaining to labels fails to remedy the substantial deficiencies of Fu et al.

Accordingly, Applicant asserts that the rejection of claims 6 and 7 under 35 USC § 103(a) as allegedly unpatentable over the Fu et al. reference is improper and respectfully requests that the rejection be withdrawn.

In view of the above arguments, the Examiner is respectfully requested to reconsider the validity of the rejection of the claims under 35 U.S.C. §103 and withdraw the rejection.

Fees

No additional fees are believed to be necessitated by this amendment. However, should this be an error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment or to credit any overpayment.

Conclusion

It is submitted, therefore, that the claims are in condition for allowance. No new matter has been introduced. Allowance of all claims at an early date is solicited. In the event that there are any questions concerning this amendment, or application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application may be expedited.

Respectfully submitted,

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